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MAR 14 1997

K970042

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

SUMMARY OF SAFETY AND EFFECTIVENESS FOR OOLI-U (TONGUE SCRAPER)

Monday, December 30, 1996

1. Telefax International, 23704-5 El Toro Road, Ste. 527, Lake Forest, CA 92630.
Contact Person: Upen Shah, Tel.: (714)-581-1447, Fax: (714)-581-1448.
2. Proprietary Name: Ooli-U
Common/Usual Name: Tongue Scraper/Tongue Cleaner
Classification Name: Tongue Scraper
3. Predicate Device: U.S. Dentek' Sakool (K961574).
4. Description of Device: The device is a formed piece of stainless steel.
5. Intended Use: The device is intended to remove plaque and food debris from the surface of the tongue.
6. Technological Characteristics:
The only known difference from the predicate device, is the material from which is made of. Ours is stainless steel material that is commonly used in dental equipment and theirs is a plastic. From using these devices, the results are the same.
7. Summary of Performance Data:
Not Applicable.
8. Conclusions Drawn From Nonclinical and Clinical Tests:
Not Applicable..